CLAIMS

What is claimed is:

1. An ophthalmic pharmaceutical composition, comprising:

about 0.003 % w/v (1R,2S,5R)-2-isopropyl-N-(4-methoxyphenyl)-5-methylcyclohexane-1-carboxamide;

about 0.14 % w/v hypromellose;

about 3.0 % w/v polyoxyl 35 castor oil;

about 0.78 % w/v sodium dihydrogen phosphate dihydrate buffer;

about 0.55 % w/v NaCl;

a sufficient amount of NaOH to provide an ophthalmic pharmaceutical composition with a pH of about 7;

purified water; and

a viscosity of less than 5 centipoise.

2. An ophthalmic pharmaceutical composition, comprising:

about 0.0014 % w/v (1R,2S,5R)-2-isopropyl-N-(4-methoxyphenyl)-5-methylcyclohexane-1-carboxamide;

about 0.14 % w/v hypromellose;

about 3.0 % w/v polyoxyl 35 castor oil;

about 0.78 % w/v sodium dihydrogen phosphate dihydrate buffer;

about 0.55 % w/v NaCl;

a sufficient amount of NaOH in order to provide an ophthalmic pharmaceutical composition with a pH of about 7;

purified water; and

a viscosity of less than 5 centipoise.

3. An ophthalmic pharmaceutical composition comprising:

about 0.003 % w/v (1R,2S,5R)-2-isopropyl-N-(4-methoxyphenyl)-5-methylcyclohexane-1-carboxamide;

about 0.14 % w/v hypromellose;

about 3.0 % w/v polyoxyl 35 castor oil;

about 0.78 % w/v sodium dihydrogen phosphate dihydrate buffer;

about 0.55 % w/v NaCl;

a sufficient amount of NaOH to provide an ophthalmic pharmaceutical composition with a pH of about 7.0;

purified water q.s to about 1.0 mL; and

a viscosity of less than 5 centipoise.

4. An ophthalmic pharmaceutical composition comprising:

about 0.0014 % w/v (1R,2S,5R)-2-isopropyl-N-(4-methoxyphenyl)-5-methylcyclohexane-1-carboxamide;

about 0.14 % w/v hypromellose;

about 3.0 % w/v polyoxyl 35 castor oil;

about 0.78 % w/v sodium dihydrogen phosphate dihydrate buffer;

about 0.55 % w/v NaCl;

a sufficient amount of NaOH to provide an ophthalmic pharmaceutical composition with a pH of about 7.0;

purified water q.s to about 1.0 mL; and

a viscosity of less than 5 centipoise.

5. The ophthalmic pharmaceutical composition of any one of claims 1–4 wherein the sufficient amount of NaOH is 1 N NaOH.

6. The ophthalmic pharmaceutical composition of any one of claims 1–5, wherein the ophthalmic pharmaceutical composition is stored in a polyolefin container.

7. Use of the ophthalmic pharmaceutical composition of any one of claims 1–6 in the manufacture of a medicament for the treatment of dry eye in a subject in need thereof; wherein a therapeutically effective amount of the ophthalmic pharmaceutical composition is to be administered to the subject.

8. Use of the ophthalmic pharmaceutical composition of any one of claims 1–6 in the manufacture of a medicament for reducing the likelihood of dry eye in a subject in need thereof; wherein a therapeutically effective amount of the ophthalmic pharmaceutical composition is to be administered to the subject.

9. Use of the ophthalmic pharmaceutical composition of any one of claims 1–6 in the manufacture of a medicament for the treatment of an ophthalmic disease or disorder that involves tear production in a subject in need thereof; wherein a therapeutically effective amount of the ophthalmic pharmaceutical composition is to be administered to the subject.

10. Use of the ophthalmic pharmaceutical composition of any one of claims 1–6 in the manufacture of a medicament for reducing the signs or symptoms of the ophthalmic disease or disorder that involves tear production in a subject in need thereof; wherein a therapeutically effective amount of the ophthalmic pharmaceutical composition is to be administered to the subject.

11. The use of claim 9 or 10, wherein the ophthalmic disease or disorder is dry eye.

12. Use of the ophthalmic pharmaceutical composition of any one of claims 1–6 in the manufacture of a medicament for treating ocular irritation involving tear production in a subject in need thereof; wherein a therapeutically effective amount of the ophthalmic pharmaceutical composition is to be administered to the subject.

13. Use of the ophthalmic pharmaceutical composition of any one of claims 1–6 in the manufacture of a medicament for reducing ocular irritation involving tear production in a subject in need thereof; wherein a therapeutically effective amount of the ophthalmic pharmaceutical composition is to be administered to the subject.

14. The use of any one of claims 7–13, wherein the ophthalmic pharmaceutical composition is to be administered topically to the subject.

15. The ophthalmic pharmaceutical composition of any one of claims 1–6 for use as a medicament.

16. Use of the ophthalmic pharmaceutical composition of any one of claims 1–6 for dry eye.